

MAR 4 - 2005

K050413
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EXHIBIT # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identification:

AMPLIFE Corporation
10F, No. 69, Sec. 3, Hue Jung Rd
Taichung, Taiwan, R.O.C

Date Summary Prepared: January 25, 2005

Contact: Mr. Laurence Yang
Tel: 0422587766
Fax: 0422587558

2. Name of the Device:

AMPLIFE Wrist Watch Blood Pressure Monitor, Model M600

Common Name or Classification Name:

Wrist Watch Blood Pressure Monitor / Auto-Inflation Oscillometric Digital Blood Pressure Monitor

3. Predicate Device Information:

The AMPLIFE Wrist Watch Automatic Blood Pressure Monitor, Model M600 is substantially equivalent to the Microlife Automatic Wrist Watch Blood Pressure Monitor, Model BP3AX1, K# 040002.

4. Device Description:

The AMPLIFE Wrist Watch Automatic Blood Pressure Monitor, Model M600 is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic semiconductor sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to

define the systolic and diastolic blood pressure and calculating pulse rate, which is a well known technique in the market called the "oscillometric method".

5. **Intended Use:**

The AMPLIFE Wrist Watch Blood Pressure Monitor, Model M600 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Wrist.

6. **Comparison to Predicate Devices:**

The AMPLIFE Wrist Watch Automatic Blood Pressure Monitor, Model M600 and the predicate device are identical in functionality and performance with the difference being the external shape of the devices, and PCB layout of the devices, performance specifications, ergonomics of the user interface, dimensional specifications, display mode and memory function, which do not make any effects on the performance of the device. The blood pressure measurements algorithm and its fundamental scientific technology are identical to the predicate device.

Both devices use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. A wrist watch cuff is inflated automatically; deflate rate is controlled but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the AMPLIFE Automatic Wrist Watch Blood Pressure Monitor, Model M600 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

- a. General Functions Test
- b. Reliability Test - Operation Conditions
- c. Reliability Test - Drop Testing
- d. Reliability Test - Storage

- e. Reliability Test - Vibrating Testing
- f. EMC Test
- g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the AMPLIFE Automatic Blood Pressure Monitor, Model M600 tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

We have performed the clinical test on AMPLIFE Wrist Watch Blood Pressure Monitor according to "Clinical Data and Analysis ANSI/AAMI – SP-10 Standard, Section 4.4.2" which outlines and summarizes clinical testing performed.

9. Conclusions:

We have demonstrated that the AMPLIFE Automatic Wrist Watch Blood Pressure Monitor, Model M600, is as safe and effective as the predicate, the Microlife Automatic Blood Pressure Monitor, Model BP3AX1, based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

AMPLIFE Corporation
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K050413

Trade Name: AMPLIFE Wrist Watch Blood Pressure Monitor, Model M600
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: February 17, 2004
Received: February 18, 2005

Dear Mr.Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 -- Mr. Ned Devine

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Page 1 of 1510(k) Number (if known): K050413Device Name: **AMPLIFE Wrist Watch Blood Pressure Monitor, Model M600****Indications For Use:**

The AMPLIFE Wrist Watch Blood Pressure Monitor, Model M600 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use X_____
(21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna R. Lechner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050413